SURGICAL SCALPEL

Background of the Invention

Surgical scalpels are used by medical personnel in connection with surgical procedures ranging from simple out-patient procedures to extraordinarily complex procedures carried out under general anesthesia. When working with such a sharp instrument, there is always a danger to medical personnel of inadvertent puncture of the skin. Aside from the injury itself, the more important concern for the punctured individual relates to the potential spread of disease from a non-sterile instrument.

The use of surgical scalpels having a retractable blade has been suggested as a means for reducing the number of such puncture wounds. Indeed, a number of patents have been issued which are directed toward surgical scalpels having retractable blades. These include, for example, U.S. Patent Nos. 5,531,754, 6,254,621, 6,041,505, 6,022,364, 6,015,419, 5,908,432, and 5,779,724. Absent from the disclosure of these referenced U.S. Patents, and any other publication of which Applicant is aware, is a means for determining whether the retractable blade of the surgical scalpel has ever been advanced. In the absence of such an indicator, it may be possible for a previously used scalpel to be mistaken for a new and sterile scalpel. It is certainly less likely that such a mistake could be made if a surgical scalpel equipped with a retractable blade were also designed to incorporate a single-use indicator which would provide a clear indication if the blade of the device were ever extended post-manufacture.

Summary of the Invention

The present invention relates to a single-use surgical scalpel offering a variety of advantages relative to prior art devices. In preferred embodiments, the surgical scalpel

of the present invention consists of three elements: a housing, a blade carrier, and a blade.

The scalpel housing is preferably molded from plastic in an injection molding procedure. As will be seen by reference to the attached drawings, the housing consists of two halves which are either ultrasonically welded together, or held closed by means of snap together features in the assembled device with the blade carrier and blade in place. While the two halves can be molded independently, in preferred embodiments the two halves are molded as a single unit with the two halves being joined by a live hinge.

When assembled, with the two halves ultrasonically welded together, the molded plastic housing has an upper and a lower radiused edge, and interior and exterior wall surfaces. In preferred embodiments, the interior walls of the molded plastic housing are ribbed, with the innermost surfaces of the ribs defining a channel for the slidable engagement of a blade carrier. The use of molded ribs, rather than simply employing an unribbed inner wall surface, offers well known advantages in the injection molding process. In addition, the ribbed bearing surface provides decreased friction in blade carrier movement when compared to the frictional forces encountered with a non-ribbed bearing surface. Other features of the channel include, an open end through which a surgical blade is extended during use, a slot through the lower radiused edge for slidable engagement of an actuator/locking fin, a single-use indicator window, and a retaining element for engaging a distal end of a leaf spring.

The molded plastic blade carrier, which is slidably engaged by the channel defined by the ribbed interior wall surface of the housing, includes a first end adapted for engaging the surgical blade, and a second end comprising a leaf spring to assist in blade retraction, the leaf spring having a proximal and a distal end. The blade carrier also

includes a central portion which includes the actuator/locking fin and a single-use indicator.

Brief Description of the Drawings

Fig. 1 is a plan view of the housing of the device of the present invention, in unassembled form.

Fig. 2 is a front end view of the housing of the device of the present invention, in assembled form.

Fig. 3 is a bottom isometric view of the housing of the device of the present invention showing two-mated halves with blade carrier and blade omitted.

Fig. 4 is a right side plan view of the blade carrier of the present invention.

Fig. 5 is a left side plan view of the blade carrier of the present invention.

Fig. 6 is a top view of the blade carrier of the present invention.

Fig. 7 is an isometric view of the fully assembled device in the blade-retracted position.

Fig. 8 is an isometric bottom view of an optional palm-support attachment.

Fig. 9 is an isometric bottom view of the optional palm-support attachment positioned on the scalpel of the present invention with surgical blade extended.

Fig. 10 is a plan view of a single-mold embodiment of the present invention.

Description of Preferred Embodiments

Referring to Fig. 1, an element of the device of the present invention is shown in plan view. More specifically, Fig. 1 depicts a molded plastic housing (12). The housing consists of a first half (14), and a second half (16), which are mated in the assembled device. While the first half (14) and the second half (16) can be independently molded prior to assembly, in preferred embodiments, the two halves

are molded as a single unit and joined by a live hinge (18) which runs longitudinally and defines a common edge of each half. The live hinge (18) is essentially a thinly molded plastic strip which holds the two halves together and, by virtue of its thinness, enables the two halves to mate without breaking the hinge. Also shown in Fig. 1 is a molded press fit with male (21) and female (20) elements designed to hold the mated halves (14 and 16) together in the assembled device prior to ultrasonic welding. Ultrasonic welding flanges (25, 27, 29 and 31) are provided to effectively and permanently weld halves 14 and 16 together following assembly. Alternatively, permanent type snap together features (not illustrated) may be used in place of the ultrasonic welding to assemble the halves 14 and 16.

The interior walls (24 and 26) of halves 14 and 16 carry molded ribs (23) which define a channel for slidable engagement of a blade carrier. As discussed briefly above, the use of a ribbed bearing surface, as opposed to unribbed interior wall surfaces, offers advantages in the injection molding process. The ribs create a thicker and stiffer wall section whole reducing the volume of the material (relative to a solid wall of equal thickness). The reduction in thick sections prevents sink marks from occurring on the outer surfaces of the handle. These sink marks are caused by the shrinkage of the plastic during the cooling portion of the molding cycle. In addition, ribbed bearing surfaces offer less frictional resistance to a moving blade carrier than would unribbed interior wall surfaces.

Item 22 is a molded retaining element designed to anchor the distal end of a leaf spring element of the blade carrier. Item 22 is dimensioned for a secure press fit in molded receiving element (19). In preferred embodiments, the retaining element is an anchoring boss which engages a ring on the distal end of the leaf spring. Item 28 is a

viewing window to provide for visual inspection of a single-use indicator.

Figs. 2 and 3 are, respectively, an end plan view and a bottom isometric view of the assembled housing in which no blade carrier or blade has been inserted. These drawings are included to provide views of specific elements of the housing which are not clearly seen in the unassembled housing halves of Fig. 1. Viewing end-on, Fig. 2 shows one end of the assembled housing contains an opening (34) in communication with the interior channel of the housing (12). Reference numeral 35 is directed toward a shimming end of a rib. Shimming ends (35) will be discussed in more detail in connection with Figs. 5 and 6. Fig. 2 also shows that the top edge (36) and the bottom edge (38) of the housing (12) are radiused for comfort and control.

Referring to Fig. 3, a scalpel of the present invention is shown isometrically, from below. Depicted is a live hinge (18), joining housing halves 14 and 16. The lower edge of the assembled housing (12) contains a slot (30) for slidable engagement of an actuator/locking fin, which is an element of the blade carrier. In preferred embodiments, a molded ramp (32) extends from one edge of the wall which defines the slot (30). The molded ramp (32) functions to retain the blade carrier in a blade-extended position during use.

Referring to Fig. 4, the blade carrier of the present invention is shown in a right side plan view. The blade carrier can be seen generally as consisting of three portions: a first end comprising a surgical blade engagement mold (40), a second end comprising a leaf spring (42) to assist in blade retraction, the leaf spring having a proximal (44) and a distal end (46), and a central portion (48) comprising an actuator/locking fin (50) and a single-use indicator (52). One of the many advantages of the present invention is that the blade carrier can be molded as

a single unit from plastic. The use of a leaf spring, rather than a metal coil spring, enables this advance over the art. Also shown in Fig. 4 is a molded anchoring ring (54) which engages the anchoring boss depicted in, and discussed in connection with, Fig. 1.

Fig. 5 is a left side plan view of the blade carrier of the present invention. The left side plan view shows features, or portions of features depicted in Fig. 4, including: surgical blade engagement mold (40), leaf spring (42), locking/actuator fin (50), and single use indicator (52). In addition, Fig. 5 shows a shimming plane (54). Shimming plane (54) is tapered and serves to increase the overall thickness of the blade carrier from the blade engagement mold, rearward. In use, as the blade is extended using the locking/actuator fin, the shimming plane (54) makes contact with a shimming end of a rib (see reference numeral 35 in Fig. 3). Ribs (23) as shown in Fig. 1, are tapered near opening 34. The taper of the rib complements the taper of the shimming surface (54) of the blade carrier edge thereby eliminating any unwanted blade movement when the blade carrier is locked in the blade-extended position. Initial contact between shimming plane (54) and a rib shimming end is made early in the travel of the blade carrier from the blade-withdrawn to the blade-extended position. The increase in thickness from the blade engagement mold, rearward, is calibrated such that the blade engagement mold portion is securely shimmed in the blade-extended position.

Line 1-1 of Fig. 6 is intended to provide a sense of the slope of shimming plane 54. One of skill in the art will recognize that the slope of an effecting shimming plane could vary dramatically depending upon the tolerances provided at the open end through which the blade extends. Fig. 6 also provides a profile view of a preferred embodiment of the single-use indicator (52). The single-use

indicator is shown as a thinly molded convex bubble of plastic, the concave side of which is seen in Fig. 5.

Referring to Fig. 7, with the surgical blade in the fully retracted position, single-use indicator 52 occupies viewing window 28, within housing 12. As the locking/actuator fin (50) is advanced to extend the surgical blade, the single use indicator (52) is irreversibly collapsed or inverted by contact with the ribbed interior wall surface. In preferred embodiments, the ribs making initial contact with the single-use indicator bubble are ramped. Ramping tends to minimize the possibility that any portion of the single-use indicator bubble (52) could be broken loose within the housing as the blade carrier is advanced. Such an occurrence would be much more likely if the bubble encountered a squared rib edge while the blade carrier was advanced.

When the surgical blade is subsequently retracted, visual observation through viewing window (28) will clearly indicate that the surgical blade has been previously extended. In the clinical setting, observation that the surgical blade has been previously extended would dictate disposal of the device. Fig. 7 also shows molded fins (55) on the housing (12) in critical gripping locations.

For overhand use, primarily in connection with gross-cutting activities, the device of the present invention can be fitted with an optional palm-support (57) enabling increased control in an overhand cutting mode. The optional support attaches, for example, by friction fit or snap fit. It will be recognized that the palm support could be molded together with the housing making it an integral (i.e. non-optional) palm support. An isometric bottom view of this optional attachment is shown in Fig. 8, and Fig. 9 shows an isometric bottom view of the optional device attached to an assembled scalpel in the blade-extended position.

The surgical scalpel of the present invention can also be fitted with an optional high intensity lighting system. The lighting system, not shown in the drawings, comprises a battery, bulb and fiber optic strand. Molded within the housing (12), preferably rearward of the channel for the blade carrier, would be a molded cavity for receiving the batter and high intensity bulb. A fiber optic strand, preferably acrylic, would be positioned adjacent the live hinge. During the molding process, an appropriately dimensioned channel could be formed for accepting a fiber optic strand. The fiber optic strand would carry light to the working end of the scalpel. An optional lens could be positioned near the terminus of the fiber optic strand to provide adjustable focus of the emitted light beam.

The high intensity bulb is typically provided with two contact legs. In a preferred embodiment, one contact leg is permanently contacted with a battery. The lighting circuit is completed when the second leg of the bulb is contacted with the battery. In preferred embodiments, movement of actuator/locking fin (50) forward into the blade-extended mode would drive the second leg into battery contact, thereby completing the lighting circuit.

Referring to Fig. 10, a single-mold embodiment of the present invention is represented. Elements common to this embodiment, and those previously described include, housing halves (14 & 16); live hinge (18); molded press fit with male (21) and female (20) elements; inner wall surface ribs (23); interior wall surfaces (24 and 26); ultrasonic welding flanges (25, 27, 29 and 31); viewing window (28); rib shimming end (35); surgical blade engagement mold (40); leaf spring (42); locking/actuator fin (50); single use indicator (52); shimming plane (54); and central portion (48) of the blade carrier. A unique aspect to this embodiment is a second live hinge (39) which joins the blade carrier assembly to the housing.